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Use of Customized Binaural Beats for the Treatment of Chronic Insomnia

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Objectives: Chronic insomnia affects 10%–15% of the population, with one-third of Western adults struggling with sleep initiation or maintenance. Binaural beats, which involve two audio frequencies, have shown the potential for enhancing sleep and mood. This study examined the efficacy of customized binaural audio tracks generated using facial analysis software to treat chronic insomnia. **Methods:** A 45-minute personalized binaural beat audio session was delivered using the Spatial app and headband (SoundHealth) to 20 participants with moderate-to-severe insomnia, according to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition and Insomnia Severity Index (ISI) criteria, over four weeks in California. Statistical analysis (paired t-test and linear mixed modeling) was used to compare baseline ISI scores to post-treatment scores, with $p<0.05$ indicating significance. The study assumed 80% power and aimed to achieve a 7-point ISI reduction. **Results:** All participants completed the study with no adverse events or full protocol adherence. The cohort was 60% White, with a 3:1 female-to-male ratio and an average age of 51.9 years. The baseline ISI was 19.8, dropping to 8.5 after four weeks, showing an 11.3-point reduction (95% confidence interval [CI]: -15 to -7.6, $p<0.001$). Mixed modeling indicated a similar ISI decrease of 11.28 points (95% CI: -14.98 to -7.57, $p<0.001$). The treatment response rate was 70%. **Conclusions:** Customized binaural beats show promise for insomnia treatment, with no adverse effects and high adherence. Most participants improved to no insomnia or subthreshold insomnia. Further research is needed to validate these results using larger samples and to assess long-term effects.

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Keywords: Chronic insomnia; Disorders of initiating and maintaining sleep; Insomnia disorder; Primary insomnia; Psychophysiological insomnia; Sleep initiation dysfunction.

INTRODUCTION

Chronic insomnia is a widespread health concern that affects a significant proportion of the global population and poses a substantial burden on personal health and healthcare systems. The prevalence of chronic insomnia varies but is generally recognized as affecting approximately 10% to 15% of the adult population, with higher rates observed in women and older adults.[1] This disorder is characterized by persistent difficulties in initiating or maintaining sleep, early morning awakenings, and significant distress or daytime impairment in important areas of functioning. These symptoms must occur at least three times per week and persist for at least three months to meet the diagnostic criteria outlined in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5)[2] and the International Classification of Sleep Disorders, 3rd Edition.[3]

The diagnosis of chronic insomnia involves a clinical assessment that includes detailed medical and sleep history, often supplemented by sleep diaries or actigraphy. Polysomnography may be employed in ambiguous cases in which other sleep disorders must be ruled out.[4] Treatment strategies for chronic insomnia are tailored to an individual's specific needs and the underlying causes of insomnia. Cognitive behavioral therapy for insomnia (CBT-I) is considered the first-line treatment and has been shown to effectively improve sleep quality and duration.[5] Pharmacological treatments are also available and considered when CBT-I is unavailable or ineffective. These treatments may include the short-term use of hypnotic medications under strict medical supervision.[6]

Understanding chronic insomnia through the lens of its

prevalence, diagnosis, and treatment is crucial for developing more effective interventions and supporting millions of people living with this condition. It is imperative that clinical practices incorporate the most current evidence-based approaches to manage and mitigate the effects of chronic insomnia.

The exploration of non-pharmacological interventions for insomnia has gained significant traction in recent years, with a particular focus on the potential therapeutic effects of binaural beats. Binaural beats, a form of auditory brainstem response that occurs when tones of different frequencies are presented separately to each ear, are hypothesized to induce changes in brainwave activity similar to those occurring in natural sleep states. The introduction of auditory stimulation is believed to facilitate relaxation and sleep by modulating activity within the thalamocortical system of the brain.

Despite growing interest in this area, efficacy in the scientific literature is mixed regarding binaural beats as a treatment for insomnia. Some studies have suggested that binaural beats can significantly improve sleep quality by reducing sleep latency and nocturnal awakenings and increasing sleep duration and depth.[7] These effects are thought to stem from the entrainment of neural oscillations to slower frequencies conducive to sleep, such as theta and delta waves. Conversely, other studies have reported minimal or no effects, indicating the need for more rigorous controlled studies to better understand the variability in responses among individuals.[8]

Given the noninvasive nature and absence of adverse effects related to binaural beats, their potential utility in the treatment of insomnia is particularly appealing. This is especially pertinent in contexts in which pharmacological treatments may be limited by side effects or contraindications. Moreover, the ability to use binaural beats in conjunction with other therapies, such as CBT-I, could offer a multimodal approach that enhances the overall treatment efficacy.

This study explored the efficacy of proprietary facial analysis software in generating customized binaural audio tracks to address chronic insomnia.

METHODS

This single-center interventional study evaluated the safety and efficacy of the spatial acoustic resonance therapy (ART) device (SoundHealth Systems) for treating moderate-to-severe insomnia. The study protocol was approved by the Western IRB (no. 20232648), and the participants were recruited from San Francisco Otolaryngology (San Francisco, CA). Participants who met the diagnostic criteria for moderate-to-severe insomnia disorder as defined by the DSM-5 and the Insomnia Severity Index (ISI) were screened, and enrolled upon meeting the eligibility criteria. For their participation, they received $150.

Device description

The ART device comprises an adjustable headband with two bone conduction transducers positioned circumferentially around the head with a central alignment over the nasal bridge (Fig. 1). This device was previously investigated for the treatment of nasal congestion by Luong et al.[9] It features Bluetooth connectivity, which allows the accompanying smartphone app to administer the therapy. The app uses the front-facing camera of a smartphone to capture and annotate multiple facial anatomical landmarks. With more than 1,000 data points collected, a virtual mesh of the participant's face is constructed, and a machine learning predictive model is used to estimate the sinus volumes of the participant. The lid-cheek junction and certain bony landmarks, such as the orbital rims, nasal bridge, zygomatic arch, and mandibular angle, are among the craniofacial features least affected by fat changes and aging. The lid-cheek junction remains relatively stable over time, as shown in serial photographs, in contrast to the more dynamic facial regions. While bony landmarks may undergo some resorption with age, they are generally less affected by fat redistribution and volume loss than other facial areas. The unique resonant frequency and associated harmonics for each participant are calculated using a proprietary algorithm with all resonant frequencies within the audible spectrum of 100 Hz to 1 kHz (Fig. 2).

Participants received 45-minute audio sessions delivered to the ART device via Bluetooth. They were instructed to don the device and activate the therapy while attempting to sleep. The headband remained in place once sleep was initiated. The participants who were unable to fall asleep within the first 45 minutes were instructed to reuse the device for an additional session.

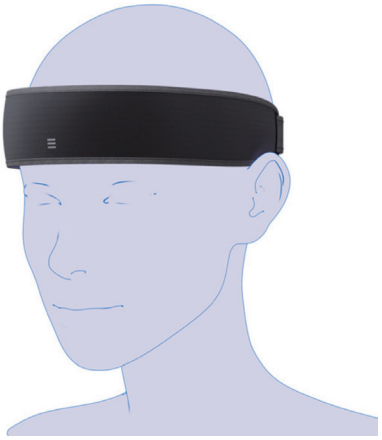

Figure 1. Spatial acoustic resonance therapy device. The device is adjustable and wraps circumferentially around the head with the emitting centers aligned with the midline nasal bridge.

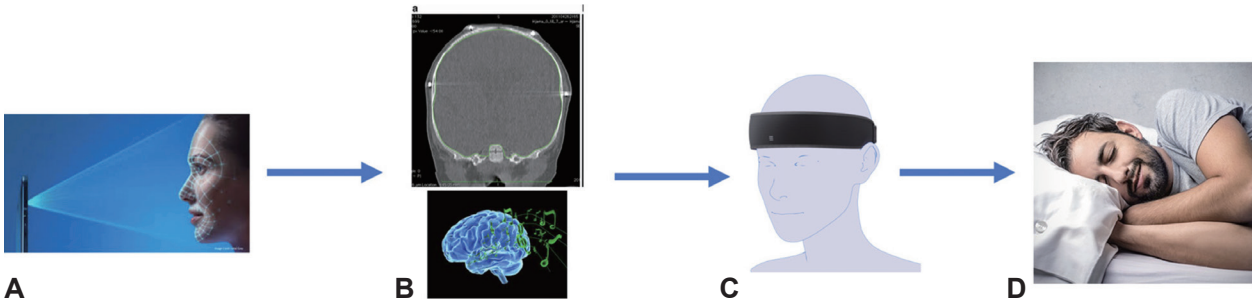

Figure 2. Process of using facial scanning to develop personalized therapy for each individual participant. A: Phone app uses the front-facing camera on a smart-phone to map multiple anatomical landmarks. B: Machine learning models used to predict sinus volumes and resonant frequencies of participants skull. C: Proprietary algorithm used to generate personalized audio file based on participants calculated bony resonant frequency. D: Sustained use of customized therapy leads to reduction of insomnia symptoms.

Eligibility criteria

Eligible participants were adults aged 18 years or older who had experienced at least three months of persistent difficulties with sleep initiation, maintenance, or early morning awakenings, with associated daytime impairment. An ISI score greater than 15 was indicative of moderate-to-severe insomnia, establishing a severity benchmark.[10]

Exclusion criteria included the use of sleep aids, both prescription and over-the-counter, as well as sedating, alerting, or antidepressant medications within three months prior to screening. Individuals with a prior diagnosis of any autoimmune or medical disorder likely to affect sleep were excluded. Pregnant females were not permitted to participate in this study.

Outcome measures

The primary outcome measure was a statistically significant reduction in ISI scores from baseline after four weeks of daily therapy. The secondary outcome was the response rate, defined as a 7-point or greater reduction in the ISI from baseline.

Safety endpoints were the absence of serious adverse events such as death, life-threatening conditions, permanent impairments, hospital admissions, or medical or surgical interventions to prevent permanent impairment.

Statistical analysis

Sample size calculations were based on 80% power and an alpha of 0.05, anticipating a 7-point decrease in the ISI, which aligns with the effect size seen in CBT-I.[11] Twenty participants were required to achieve this power.

Data were presented using graphs and descriptive statistics. Categorical variables were reported as counts and percentages, while continuous variables were summarized as means, standard deviations, standard errors, and 95% confidence intervals. ISI score changes from baseline to the four-week mark were analyzed using paired t-tests and linear mixed models with repeated measures. These models accounted for demographic variables and yielded an adjusted treatment effect estimate.

Table 1. Patient demographics

Variables	Data
Age (yr)	51.9±14.9
Race	
White	12 (60)
Asian pacific islander	5 (25)
Others	3 (15)
Hispanic ethnicity	7 (35)
Female sex	15 (75)

Data are presented as mean±standard deviation or number (%)

Table 2. Change in Insomnia Severity Index

	Mean	95% confidence interval	*p*-value*
Baseline	19.8	17.5, 22.0	-
Week 4	8.5	5.4, 11.6	-
Change	-11.3	-15, -7.6	<0.001

**p*-value is based on paired t-test. -, not applicable

The clinical significance threshold was set at a 7-point or greater reduction in ISI from baseline, matching the accepted impact of CBT-I to maintain high sensitivity and specificity for identifying moderate-to-marked improvements in participants.[11]

RESULTS

A total of 20 participants were recruited for the study, as shown in Table 1, comprising 5 males (25%) and 15 females (75%). The demographic breakdown included 12 White (60%), 5 Asian/Pacific islanders (25%), and 3 participants of other ethnicities (15%). Most participants were non-Hispanic (65%), while the remaining 35% identified as Hispanic. The mean age of the participants was 51.9 years (SD=14.9).

Data analysis revealed a significant reduction in the ISI

scores post-intervention (Table 2). The mean baseline ISI score was 19.8 (SD=4.8), which decreased to 8.5 (SD=6.6) at the four-week follow-up, marking an average reduction of 11.3 points (95% confidence interval [CI]: -15 to -7.6, p<0.001). Univariable analysis shown in Table 3 confirmed this finding, showing a similar average decrease in ISI scores of 11.28 points (95% CI: -14.98 to -7.57, p<0.001). These reductions remained statistically significant after adjusting for demographic variables, such as age, sex, race, and ethnicity.

Further analysis considering the secondary endpoint revealed a response rate of 75% (15/20 participants), achieving a 7-point or greater reduction in ISI scores from baseline. Logistic regression modeling showed no statistically significant association between demographic factors (age, sex, race, and ethnicity) and the likelihood of responding to therapy. Adherence to therapy, as per self-reporting, was 100% among participants. Additionally, 45% (9/20) of participants achieved an endpoint ISI score of 7 or less, indicating complete resolution of clinically significant insomnia (Fig. 3A).

Table 3. Linear regression models with repeated measures for Insomnia Severity Index

Variable	Regression coefficient (95% CI)	p-value
Week 4 vs. baseline	-11.3 (-15.0, -7.6)	<0.001
Age per year	-0.03 (-0.18, 0.12)	0.679
Male vs. female	-3.4 (-8.85, 2.04)	0.202
White vs. non-White	-2.8 (-8.89, 3.29)	0.342
Hispanic vs. non-Hispanic	-0.42 (-6, 5.16)	0.875

CI, confidence interval

DISCUSSION

Treatment with binaural beats has demonstrated effectiveness in enhancing subjective sleep quality and mood, as evidenced by previous studies.[12,13] This auditory stimulus is played at slightly different frequencies in each ear, leading to the perception of a third, illusory tone by the brain. Theoretically, this phenomenon can improve sleep quality and subjective satisfaction by promoting an increase in the delta brainwave activity, which is associated with deep restorative sleep. Further empirical investigation, including the monitoring of brainwave patterns during the application of binaural beats, is necessary to substantiate this hypothesis.

The findings of this study provide compelling evidence of the efficacy of ART in treating moderate-to-severe insomnia. The significant decrease in ISI scores from baseline to the four-week mark underscores the potential of this non-pharmacological intervention as a beneficial therapeutic option for individuals with chronic insomnia. Notably, the average decrease in ISI scores by 11.3 points after the intervention indicated a substantial improvement in sleep quality, which was both clinically and statistically significant. The downward slope of the ISI results from the self-matched patients and the overall mean in Fig. 3B corroborate this. This improvement is consistent with the accepted impact of CBT-I, as suggested by the established clinical significance threshold of a 7-point reduction in ISI scores.[11]

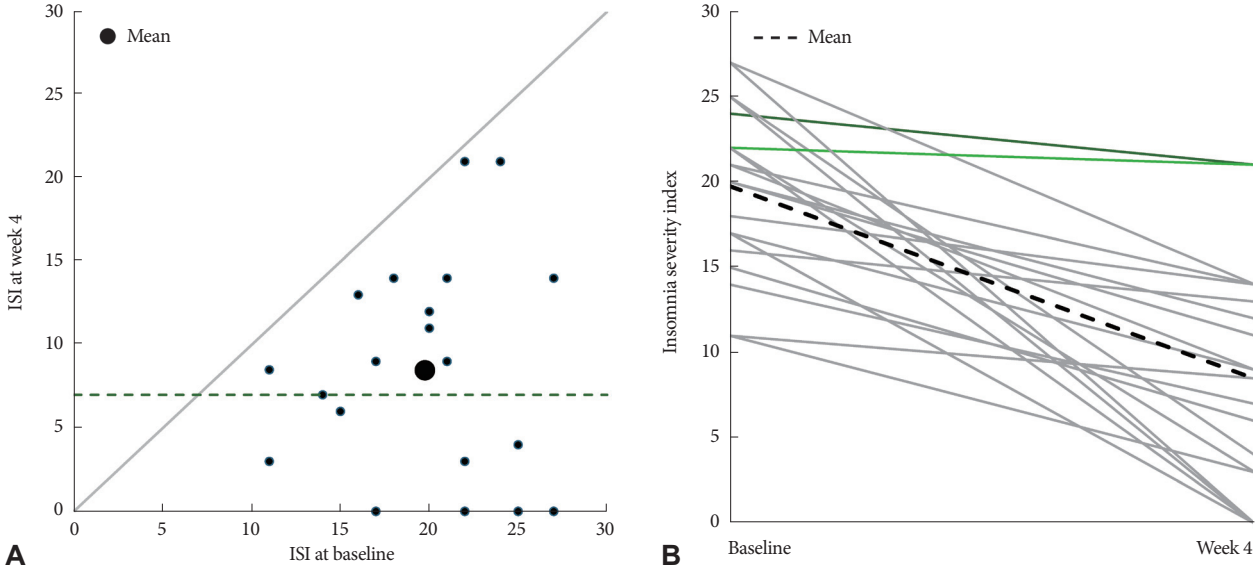

Figure 3. Insomnia severity index (ISI) baseline vs. week 4 endpoint. A: ISI of study participants represented on plot graph comparing baseline and week 4 endpoint scores. Dotted line represents ISI of 7, which represents the threshold of insomnia diagnosis based on ISI. B: Participant self-matched ISI scores from baseline and 4-week endpoint. Disclaimer: The spatial device is not yet FDA approved for the treatment of chronic insomnia. Current randomized controlled trial is underway.

The observed reduction in ISI scores post-intervention persisted even after controlling for demographic variables (Table 3), including age, sex, race, and ethnicity, underscoring the robustness of the effect of the ART device. The lack of a statistically significant association between these demographic factors and the response rates suggests that the efficacy of the ART device transcends individual differences. This is particularly relevant given the diversity of the study sample, which included varied racial and ethnic backgrounds, thus enhancing the generalizability of the findings.

The high response rate of 75%, indicating a 7-point or greater reduction in ISI scores, further attests to the effectiveness of ART intervention. In addition to the high rate of reduction in ISI scores, 45% of the study participants reported resolution of insomnia based on ISI scores. Participants' adherence to therapy, reported at 100%, suggests that the intervention was well-received, acceptable, and feasible for daily use. This high adherence rate may be attributed to the noninvasive nature of the therapy and the ease of integrating it into the nightly routine of the participants.

Given the growing interest in and need for effective non-pharmacological interventions for chronic insomnia, the findings of this study are particularly timely. The use of proprietary facial analysis software to customize binaural audio tracks represents an innovative approach for personalized medicine in sleep therapy. However, this study has some limitations. Self-reported adherence does not reflect the actual quality of the intervention, which can be better measured through objective adherence monitoring. Additionally, the individual breakdown of analyses according to demographic factors, although not reported here, may provide further insights into the nuances of treatment responses among diverse population subgroups.

Future research should replicate these findings in large-scale randomized sham-controlled multicenter trials with longer follow-up periods to determine the long-term efficacy and safety of the device. Moreover, comparative studies with other pharmacological and non-pharmacological interventions could reveal the relative effectiveness and potential synergies between treatment modalities. Given the noninvasive and cost-effective nature of binaural beats therapy, as well as the positive outcomes of this study, including high adherence rates, further exploration of this treatment is warranted.

In conclusion, ART, with its novel application in customized binaural beats, appears to be a promising intervention for the management of chronic insomnia. This study contributes to the body of evidence supporting non-pharmacological approaches for sleep disorders and highlights the potential of innovative technologies to advance treatment options for individuals with chronic insomnia.

Conflicts of Interest

Vivek Mohan, Bryant Lin, Peter Hwang, Paramesh Gopi, and Clete Kushida: Financial support provided by SoundHealth. All remaining authors have no potential conflicts of interest to disclose.

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